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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,685	11/07/2001	Kurt E. Petersen	22660-0019 DIV 2	1753
7590 04/20/2004			EXAMINER	
William Schmonsees Heller Ehrman White & McAuliffe 275 Middlefield Road Menlo Park, CA 94025-3506			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/005,685

Applicant(s)

PETERSEN ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81,82,84-90,92-100,102-108,110-136,227 and 228 is/are allowed.
- 6) ☒ Claim(s) 54-56,58-60,62,63,65-68,70-72,74,75,77-80,215-226 is/are rejected.
- 7) ☒ Claim(s) 57,61,73,83,229 and 230 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 54-63,65-68,70-75,77-82,84-90,92-100,102,108,110-136 and 215-230.

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***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 54-56, 58-60, 62, 63, 65-68, 70, 74, 75 and 77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Wilding et al.(US 5,726,026) and Jones (WO 95/02049).

The reference of Anderson et al. discloses a nucleic acid purification method which includes a cell lysing region, a nucleic acid capture region, a reaction chamber (connected or coupled to the other chambers), a detection chamber and a reagent chamber connected to the reaction chamber (See column 6, line 44 to column 12, line 45). With respect to the solid phase binding within the lysing region, the reference discloses the use of posts (1908) and binding reagents (1912). With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28). The reference discloses the use of a reagent chamber prior to amplifying the purified nucleic acids (See column 10, lines 34-39).

With respect to claims 54, while the reference of Anderson et al. discloses a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12).

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells (See column 9, lines 40-49).

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and

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expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysing chamber.

While the reference of Anderson et al. discloses the use of solid phase material or structures (1908, 1912) for capturing the sample components as the sample flows through the lysing chamber (See column 39, line 66, to column 40, line 54), Claim 54 differs further by reciting that the lysing chamber “contains at least one filter for capturing the sample components by size exclusion as the sample flows through the lysing chamber”.

The reference of Jones discloses that it is known in the art to provide a lysing chamber (21) with a filter (22) for capturing the sample components by size exclusion as the sample flow through the lysing chamber (See page 4, first full paragraph and the paragraph bridging pages 13 and 14). Note the lysing chamber is in fluid communication with an analyte capture region (27).

Additionally, the reference of Wilding et al. discloses the use of a filter structure (18) that can include specific binding as employed by the primary reference is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to employ a size exclusion filter in the chamber of the primary reference for the known and expected result of providing a means recognized in the art for retaining a desired sample within a lysing chamber while concentrating the sample from a sample solution. The use of a size exclusion filter over specific binding means would have been obvious when separation of a subpopulation of cells is not required and would simplify the construction and use of the device.

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With respect to claims 55, 56, 58, 60, 62 and 63, the reference of Anderson et al. discloses steps of amplification, adding reagents, detection of analyte and the use of ultrasonic energy (See the discussion above with respect to the disclosure of Anderson et al.).

With respect to the use of agitating particles or beads of claim 65, the reference of Anderson et al. discloses the use of lysing particles in the chamber (See column 7, lines 1-7).

With respect to the presence of a lysing buffer of claims 66, it would have been obvious to one of ordinary skill in the art to provide reagents and/or buffers which are proper for creating the proper environment for cell lysing while maintaining the viability of the sample and efficiency of the system.

With respect to the use of an ultrasonic horn of claims 67, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum transducer to employ so as to create the proper ultrasonic energy required for efficient cell lysis.

With respect to the washing of claim 68 and capture material of claims 70, the reference of Anderson et al. discloses solid phase binding of nucleic acids and washing (See column 7, lines 23-52).

With respect to claim 74, the reference of Nelson et al. discloses a nucleic acid capture configuration and method of use that includes a waste chamber and discloses enriching the sample containing the nucleic acid target by using the disclosed enrichment configuration.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to enrich the nucleic acids released from the lysing chamber of the modified primary reference of Anderson et al. for the known and expected result of providing the advantages associated with

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the configuration of the enrichment process of Nelson et al. over a “on-line” or “single flow path” (column 1, lines 55-66) employed by Anderson et al. That is, all of the sample fluid flows through the detection portion of the device.

With respect to the volumes of sample relative to the volume of the capture chamber recited in claims 75, 79, and 80, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

With respect to the volumes recited in claims 77 and 78, while still maintaining the benefits associated with enrichment disclosed by the reference of Nelson et al., it would have been obvious to one of ordinary skill in the art to determine the optimum volume of the lysis chamber and/or volume of sample to employ based merely on the concentration of the target analyte in the sample to be detected while maintaining the detection efficiency of the system.

5. Claims 71 and 215-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Wilding et al.(US 5,726,026) and Jones (WO 95/02049) taken further in view of Hansmann et al.(US 5,707,799) and Cantor et al.(US 5,795,714).



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The combination of the references of Anderson et al., Nelson et al., Wilding et al. and Jones has been discussed above.

With respect to claims 71 and 215, while the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to employ an array of structures extending into a chamber and having an aspect ratio (length to width) of at least 2:1 (See column 3, lines 47-55; column 6, lines 57-67; and column 9, lines 34-36) for capturing a desired analyte.

The reference of Cantor et al. discloses that it is known in the art that an array of binding probes can be used to capture nucleic acids for detection as is done in the reference of Hansmann et al. or the array of probes can be used to capture and elute a target analyte as is done in the reference of Swedberg et al. (See column 4, lines 17-25, and column 4, line 66, to column 5, line 10).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the array of structures disclosed by the reference of Hansmann et al. in the chamber of the primary reference of Nelson et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, capture of a desired analyte. The reference of Hansmann et al. discloses the use of the array of

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structure is advantageous over other know art recognized capture devices because of its dimensional reproducibility (See column 1, lines 21-40).

With respect to claims 216-222, the reference of Anderson et al. discloses steps of amplification, adding reagents, detection of analyte and the use of ultrasonic energy (See the discussion above with respect to the disclosure of Anderson et al.).

With respect to the volumes of sample relative to the volume of the capture chamber recited in claims 223-226, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

6. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Wilding et al.(US 5,726,026) and Jones (WO 95/02049) taken further in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Anderson et al., Nelson et al., Wilding et al. and Jones has been discussed above.

The above claim differs by reciting the use of a heater in combination with the capture chamber.

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The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure and heat the chamber for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

7. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Wilding et al.(US 5,726,026) and Jones (WO 95/02049) taken further in view of Brunner et al.(US 5,777,141).

The combination of the references of Anderson et al., Nelson et al., Wilding et al. and Jones has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 215-226 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 and 103-107 of copending Application No. 09/513,443 in view of Anderson et al.(US 6,168,948) or Wilding et al.(US 5,726,026 or 5,928,880).

Claims 18-22 and 103-107 of the claims of Application '443 encompass a method of separating an analyte from a fluid sample that includes an extraction region and sample volume limitations similar to the claims of the instant application.

The instant claims differ by reciting additional method steps and associated structure with respect to lysing the sample and reacting the analyte separated in the extraction region.

The references of Anderson et al. and Wilding et al. both disclose that it is known in the art to include cell lysing steps and structures for preparing a liquid sample for analyte extraction and the use of reaction steps and detecting steps for analyzing the extracted analyte (nucleic acid) (See the discussions of these references previous of record).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '443 with the additional lysing and reaction steps and components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

This is a provisional obviousness-type double patenting rejection.

10. Claims 54-56, 58-60, 62, 63, 65-68, 70-72, 74, 75 and 77-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 and 103-107 of copending Application No. 09/513,443 in view of Anderson et al.(US 6,168,948) and Wilding et al.(US 5,726,026 or 5,928,880) taken further in view of Jones (WO 95/02049).

Claims 18-22 and 103-107 of the claims of Application '443 encompass a method of separating an analyte from a fluid sample that includes an extraction region and sample volume limitations similar to the claims of the instant application.

The instant claims differ by reciting additional method steps and associated structure with respect to lysing the sample and reacting the analyte separated in the extraction region.

The references of Anderson et al. and Wilding et al. both disclose that it is known in the art to include cell lysing steps and structures for preparing a liquid sample for analyte extraction and the use of reaction steps and detecting steps for analyzing the extracted analyte (nucleic acid) (See the discussions of these references previous of record).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '443 with the additional lysing and reaction steps and components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

While the reference of Anderson et al. discloses the use of solid phase material or structures (1908, 1912) for capturing the sample components as the sample flows through the lysing chamber (See column 39, line 66, to column 40, line 54), Claim 54 differs further by reciting that the lysing chamber "contains at least one filter for capturing the sample components by size exclusion as the sample flows through the lysing chamber".

The reference of Jones discloses that it is known in the art to provide a lysing chamber (21) with a filter (22) for capturing the sample components by size exclusion as the sample flow through the lysing chamber (See page 4, first full paragraph and the paragraph bridging pages 13 and 14). Note the lysing chamber is in fluid communication with an analyte capture region (27).

Additionally, the reference of Wilding et al. discloses the use of a filter structure (18) that can include specific binding as employed by the primary reference is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to employ a size exclusion filter in the chamber of the primary reference for the known and expected result of providing a means recognized in the art for retaining a desired sample within a lysing chamber while concentrating the sample from a sample solution. The use of a size exclusion filter over specific binding means would have been obvious when separation of a subpopulation of cells is not required and would simplify the construction and use of the device.

This is a provisional obviousness-type double patenting rejection.

11. Claims 54-56, 58-60, 62, 63, 65-68, 70, 75 and 77-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-29 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948).

Claims 14-29 of application '590 encompass a lysing method and associated structure for releasing an analyte from a liquid sample.

The above claims differ by reciting additional method steps which include analyte extraction of the lysed sample and reaction and detection of the extracted sample.

The reference of Nelson et al. discloses a method for extracting an analyte from a liquid sample which includes an extraction region for capturing and eluting a desired analyte (See discussions of Nelson et al. above).

The references of Wilding et al. and Anderson et al. disclose that it is known in the art to provide a microchip device with cell lysing components and reaction and detection components (See the entire disclosure and discussion of these references above).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '590 with the additional lysing components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

With respect to the claimed reagents and reaction chambers and analysis chambers for nucleic acid, the references of Wilding et al. and Anderson et al. also discloses these features for detection of nucleic acid samples (See Figures 11A and 11B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the system of application '590 with reagent chamber, reaction chamber, detection chambers, etc. for the known and expected result of providing a device which is capable of extracting and detecting nucleic acid samples as is suggested by the prior art references.

This is a provisional obviousness-type double patenting rejection.

12. Claims 71 and 215-226 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-29 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

While the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.



The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Nelson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

This is a provisional obviousness-type double patenting rejection.

13. Claim 72 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-29 of copending Application No.

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09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Brunner et al.(US 5,777,141).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

14.

This is a provisional obviousness-type double patenting rejection

15. Claims 72 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-29 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

This is a provisional obviousness-type double patenting rejection

***Allowable Subject Matter***

16. Claims 81, 82, 84-90, 92-100, 102-108, 110-136, 227 and 228 are allowed.
17. Claims 57, 61, 73, 83, 229 and 230 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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18. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 57, 61, 81, 82, 84-90, 92-100, 102-108, 117-136 and 227-230, while the prior art of record discloses the use of reactions chambers which are incorporated into or coupled to the channel/chamber systems, the prior art of record fails to teach or fairly suggest 1) a reaction chamber incorporated into the channel/chamber cartridge which protrudes from the rest of the cartridge and is inserted into a thermal sleeve for heating or cooling control; 2) a reaction vessel coupled to the cartridge such that the reaction vessel can be inserted into a thermal sleeve for heating or cooling control.

With respect to claim 73, while the prior art of record disclose forming a lysate in a cartridge device wherein the lysate is forced into an extraction/elution chamber, the prior art of record fails to teach or fairly suggest the additional step of forcing the lysate to recirculate through the capture region.

### ***Response to Arguments***

19. Applicant's arguments filed 02 Feb. 2004 have been fully considered but they are not persuasive.

With respect to the rejection of Claims 54-63, 65-68, 70-75 and 77-80, Applicants argue that the rejection of the claims over the combination of the references of Anderson, Nelson and Wilding is improper for the following reasons: i) Both of the references of Anderson and Wilding capture cells on the walls of the lysing chambers using specific binding sites while the instant claims (as amended) require a filter that captures sample components by size exclusion.

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ii) The use of a size exclusion filter provides advantages not realized by the capture means of the references.

In response, the rejection of the claims has been modified in view of the new limitation added to the claim. As stated in the new rejection of the claims, the reference of Jones clearly suggests the use of a size exclusion filter with a lysing chamber. One of ordinary skill in the art would recognize that a size exclusion filter can be used when not required to separate subpopulations of cells within a sample. The use of the filter suggested by Jones would inherently provide the advantages mentioned by Applicants.

For these reasons the rejection of the claims over the combination of the references of Anderson, Nelson, Wilding and Jones will be maintained.

With respect to the rejection of Claims 215-226, 229 and 230, Applicants argue that the rejection of the claims over the combination of the references of Anderson, Nelson and Wilding taken further in view of the references of Hansmann and Cantor is improper for the following reasons: i) Applicants' method is completely different from the method shown in the reference of Hansmann because the reference of Hansmann is for the capture and detection of analyte not the capture and elution of analyte. ii) The reference of Hansmann does not include a fair teaching that one could elute from the structures of Hansmann. iii) One of ordinary skill in the art would not be motivated to provide the enrichment channel of Nelson with the structures of Hansmann in the absence of any suggestion in the reference of Hansmann. iv) The teaching in the reference of Cantor that target nucleic acid may be eluted from a probe array does not instruct or suggest to one of ordinary skill in the art to employ the structures of Hansmann in the enrichment channel of Nelson to capture and elute material.

In response, the reference of Hansmann was relied upon as a tertiary reference that displays to one of ordinary skill in the art an alternative means recognized in the art for capture or binding of target analyte. Specifically, the reference of Hansmann instructs or suggests to one of ordinary skill in the art that the use of the disclosed structures would be advantageous in view of the improved uniformity and efficiency of capture related to the capture structures disclosed by the reference of Hansmann. Clearly the level of skill in the art of analytical chemistry would allow one of ordinary skill in the art to recognize in view of the disclosure of the references before them that the use of these structures is not limited to the device of Hansmann and can be used in any system that involves specific binding to capture a desired analyte. In particular, in a system as disclosed by the references of Anderson and Nelson for the same advantages discussed by the reference of Hansmann. The reference of Cantor was cited to establish that when using nucleic acid specific binding pairs, it is known in the art to elute the captured nucleic acid from the binding probes. It is noted that the reference of Hansmann discloses that nucleic acid probes can be used on the disclosed structures.

For these reasons the rejection of the claims over the combination of the references of Anderson, Nelson, Wilding, Jones, Hansmann and Cantor will be maintained.

Applicant is reminded that the claims are still rejected under obviousness-type double patenting. Applicants' previous response indicated that a terminal disclaimer would be filed. No terminal disclaimers have been made of record and the instant response is silent as to the obviousness-type double patenting rejections and/or the intention to file terminal disclaimers.

### ***Conclusion***

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20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

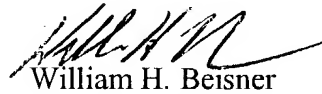
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB